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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,738	05/24/2000	MICHAEL BLATT	2186PB-1	2749

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EXAMINER	
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ART UNIT	PAPER NUMBER
1653	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/509,738	Applicant(s) BLATT ET AL.	
	Examiner Karen Cochrane Carlson, Ph.D.	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2003 and 18 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-20 and 57-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-20 and 57-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

This Office Action is in response to Paper #24, filed March 10, 2003 and Paper #25, filed July 18, 2003. Claims 3 and 21-56 have been canceled. Claim 1, 2, 4-20, and 57-78 are currently pending and are under examination. Paper #24 was filed before the previous Office Action was mailed. A supplemental office action did not follow because Paper #24 was not matched to the file until Paper #25 was filed. Therefore, this Office Action will be not be made final.

It would be helpful if Applicants notified the Examiner promptly when a supplemental response is filed to stream-line prosecution. The Examiner appreciates Applicants addressing in their response Paper #25 the issues raised in the previous Office Action as they relate to the newly added Claims in Paper #24.

Priority is set to September 30, 1997.

Withdrawal of Objections and Rejections

The rejection of Claims 18-20 and 57-65 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, with reference to SEQ ID NO: 4 is withdrawn.

Objections and Rejections

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18, 20, 57-63, and 66-78 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to fragments having biological activity. A fragment can be glycine, having a biological activity having nothing to do with ABA responses. Thus, these biologically active fragments lack written description.

The specification does not describe variants of SEQ ID NO: 2, for example see Claim 18, to include those having per cent homology to these sequences, that have the ability to increase ABA mediated control of ion channels.

Claim 20 is a "reach through claim", drawn to signaling components not described in the specification, but to be found by the performance of a method. Thus, the specification does not describe the signaling components.

Therefore, the claims lack written description.

At page 10, para. 2 of the response, Applicants point out where in the specification biological activity for fragments and variants can be found. However, the activity language is open in the claims. Applicant may wish to amend the claims to recite "wherein said biologically active fragments participate in ...".

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 19 presents new matter. While Applicants point to the specification at pages 5-6 to provide basis for the amendment to Claim 19, this passage

refers to two hybrid systems involving fusion proteins and recombinant technology. As written, Claim 19 appears to be directed to a binding assay between two proteins, and this is not set forth in the specification.

Applicants argue at page 11 that the two-hybrid system is only one method by which protein-protein interaction can be evaluated. The entire passage at pages 5-6 reads:

The protein of the present invention may be used in screens to detect protein-protein interactions. In particular, the protein may be used to screen for other members of a signal transduction pathway. One suitable method is the so-called two-hybrid system, in which the DNA binding domain of the GAL4 protein is fused to the protein of the present invention. A second plasmid is constructed comprising the activation domain of the GAL4 protein fused to a protein (or peptide or polypeptide) under investigation. Interaction of the protein of the present invention and the protein under investigation leads to transcriptional activation of a reporter gene, such as detection by expression of a Gal1-lacZ gene fusion.

A depiction follows:

SEQ ID NO: 2 +++ X
| | === somehow all will interact with DNA to express Gal1-lacZ reporter
DBD(GAL4) AD(GAL4) gene

Claim 19 reads:

A method of screening for protein-protein interaction comprising

a) contacting a protein according to any one of Claims 1-18 with an expressed candidate ABA signaling component; and

b) detecting interaction between said protein and said ABA signaling component.

A depiction follows:

SEQ ID NO: 2++++ ABA signaling component

In the passage at pages 5-6, no specific protein X is mentioned, and no interaction that is specific between SEQ ID NO: 2 and the protein X is determined, but a by-product reaction due to the fusion of GAL4 domains. Claim 19 is drawn to a binding or interaction assay that is specific between SEQ ID NO: 2 and an ABA signaling component. This method is not described in the passage because the detection of something downstream has nothing to do with how one would detect a specific interaction between compounds. Therefore, the claimed method is new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4-20, 57-78 are rejected under of 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the claims, "ABA" is indefinite because it is an acronym. Absicisic acid should be spelled out in at least the independent claims.

The term "homology" is qualitative and not quantitative. The term "identity" would more clearly define a protein that shares at least 50% identity to SEQ ID NO: 2, for example.

Claim 18 refers to variants. If not, it is not clear what a variant of a structure is.

In Claim 19, it is not clear how the interaction of the proteins is determined.

In Claim 20, it is not clear which protein is selected.

With reference to Claim 20, Applicants urge that it is an ABA signaling component protein that is being selected. Again, which? There is no description in the specification regarding what that component may be.

Claim 20 is rejected under 35 U.S.C. 102(b) as being anticiapted by Leung et al. (1994; Science 264:1448-1452). Leung et al. teach *Arabidopsis* ABA response gene product ABI1, which is a calcium-modulated protein phosphatase. This phosphatase comprises and EF hand consensus sequence as shown in Fig. 4. Further, Leung et al teach that the stomatal opening as well as some of the electrogenic units involved (such as plasma membrante H pump and inward rectifying K channels) are sensitive to protein phosphorylation (page 1451. Leung et al. also teach that Abl1 may interact with $p34^{cdc2}$ (page 1450, col. 2, para. 2). Thus, $p34^{cdc2}$ anticipates Claim 20.

Applicants did not address the anticipation of Claim 20.

No Claims are allowed.

Again, as noted in the previous Office Action, it appears that if Claim 1 were amended to recite the following it would be allowable:

An isolated protein comprising:

(i) a hydrophobic C-terminus;

(ii) at least one coiled coil region;

(iii) an EF-hand consensus sequence;

(iv) a nucleotide binding site; and optionally

(v) a hydrophilic N-terminus;

wherein said protein inhibits absicisic acid (ABA) mediated control of ion channels.

Of course, other amendments to the claims would have to take place to overcome all of the rejections above.

This is a very broad claim. However, the structural descriptions are known in the art. These structural regions are pointed out in the specification and demonstrated across proteins as shown in Figure 10. The combination of the structures have not been found in the prior art. Further, the elicited activity for this structure is not found. The claim is enabled. Hopefully, this draft claim will provide Applicants with a clear demonstration of amendments to the claims that would over come the rejections made herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER